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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,449	02/11/2004	Winthrop D. Childers	200309745-1	4805

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EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	

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07/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,449	CHILDERS ET AL.	
	Examiner	Art Unit	
	Kristen C. Matter	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/11/04 and 6/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 is redundant on itself. Examiner is unsure what is involved with configuring the controller because there appears to be a typo.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-13, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Poole (US 6,158,431).

Regarding claims 1 and 28, Poole discloses an inhaler with a medicament supply (80), an ejector (16) having a performance characteristic, and a controller configured to actuate the ejector using an operational parameter including a correction factor based on the performance characteristic of the ejector (column 5, line 65-column 6, line 2, and column 7, lines 1-5).

Regarding claims 8-11, Poole discloses that the droplet firing rate, drop size, dosage (number of drops), pressure, and temperature can all be controlled by the controller based on the

performance characteristic and correction factor (column 8, lines 50-55, column 11, lines 5-15, column 12, lines 50-55, column 13, lines 10-15).

Regarding claims 12 and 13, the correction factor disclosed by Poole can be considered static or dynamic. For example, as humidity changes, the correction factor changes accordingly (Figure 10) and would therefore be considered dynamic. However, if humidity remains the same, the correction factor can be considered a static correction factor based on the drop drying length, temperature, and drop size.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poole (US 6,158,431). Although Poole does not specifically disclose the recited calibration steps (i.e., determining a correction factor to produce the target output from the inhaler), the device disclosed by Poole has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing Poole's device, to perform the recited method steps of the instant claim in order to calibrate the inhaler. In addition, Poole does explicitly disclose that the inhaler and sensors should be calibrated so that the desired performance

characteristic can be achieved by varying the operational parameters (column 12, line 40-column 13, line 15).

Claims 6, 7, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poole (US 6,158,431), as applied to claims 1 and 15 above, and further in view of Poole et al. (US 5,278,626).

Regarding claims 6 and 7, Poole does not explicitly disclose determining the ejected drop volume or weight. However, Poole does disclose that the droplet inspection determines the size, shape, and concentration of the droplets. Determining droplet volume or weight from this information is considered a design consideration to one of ordinary skill in the art. It appears that Poole's device is fully capable of determining droplet volume and weight from the collected information. In addition, Poole et al. teaches that determining volume from droplet diameter in an inhaler is well known in the art (column 6, line 65-column 7, line 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use drop volume or weight for the performance characteristic instead of drop size for a more accurate determination of the amount of medication being delivered to the patient with each drop.

Regarding claims 16-20, the modified device disclosed by Poole and Poole et al. has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified Poole device, to perform the recited method steps of the instant claim. In addition, Poole discloses calibrating the inhaler and sensors so that the desired

performance characteristic can be achieved by varying the operational parameters (column 12, line 40-column 13, line 15).

Claims 1-5, 8-14, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (US 6,234,167) in view of Poole (US 6,158,431).

Regarding claims 1 and 28, Cox et al. discloses an inhaler comprising a medicament supply (23), an ejector having a performance characteristic and a controller configured to actuate the ejector using an operational parameter with a correction factor based on the performance characteristic of the ejector (column 7, lines 15-30 and column 8, lines 1-45). To the extent, if any, that Cox et al. is silent as to a correction factor, Poole teaches that it is well known to use correction factors for adjusting operational parameters of inhalers based on performance characteristics to produce a desired dosage for a user. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a correction factor in the device disclosed by Cox et al. as taught by Poole in order to produce the desired performance characteristic in a given environment.

Regarding claims 2-5 and 14, Cox et al. further disclose a accumulator with a compliant member to regulate pressure within in the accumulator (45), a valve (35) intermediate the medicament supply and accumulator that is operated by the controller to increase pressure in the accumulator, and a pressure sensor (48) to sense the pressure in the accumulator (see column 5, lines 20-45).

Regarding claims 8-11, Cox et al. discloses that the operational parameters controlled can include drop ejection frequency, the dosage (i.e., total drops ejected), medicament pressure (via

the valve), or ejector temperature (via a heater) (see column 6, lines 60-67, column 7, lines 15-30 and column 8, and lines 5-10).

Regarding claims 12 and 13, the correction factor disclosed by Poole can be considered static or dynamic. For example, as humidity changes, the correction factor changes accordingly (Figure 10) and would therefore be considered dynamic. However, if humidity remains the same, the correction factor can be considered a static correction factor based on the drop drying length, temperature, and drop size.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-11 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/375,794. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. The instant claims 1 and 28 are broader versions of the copending claim 1 (i.e. the instant claims do not include the structural element of the fluid-based solute medicament as in the copending claim 1). In the instant claims, the structural elements are included in the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1, 6-11, and 28 do not differ from the scope of the copending claims 1-8.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 14, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 10/777448. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claims and the instant claims are minor and obvious from each other. The instant claims 1 and 28 are broader versions of the copending claim 1 (i.e. the instant claims do not include the structural element of a fluid medicament as in the copending claim 1). In the instant claims, the structural elements are included in the copending claim 1. Any infringement over the copending application would also infringe over the instant claims. Hence, the instant claims 1-4, 14, and 28 do not differ from the scope of the copending claims 1-32.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hess et al. and Bonney et al. are cited to show other relevant medicament dispensers with controllers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

K C Matter

Kristen C. Matter
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
6/18/07